Empi Continuum

Complete Electrotherapy System

USER'S MANUAL

- Read this manual carefully before operating the Continuum™
- Visit us at www.empi.com

Empi

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Product Description

The Empi Continuum is a state-of-the-art, multifunction electrotherapy device. It has the ability to provide two channels of conventional neuromuscular electrical nerve stimulation (NMES), conventional transcutaneous electrical nerve stimulation (TENS) and Pulsed DC Current (Pulsed Galvanic Stimulation) electrotherapy. This wide-ranging capability allows the clinician to employ electrotherapy throughout the healing cycle with a single device. Furthermore, programmability of the device allows the clinician to customize the treatment to meet the individual needs of each patient.

The Continuum (NMES) feature produces an electrical stimulus that, when properly applied, activates specific muscles or muscle groups. The waveforms are fully programmable for maximum treatment flexibility.

The Empi Continuum has a Pulsed DC Current feature that can be used for increasing the local blood circulation.

The Empi Continuum has thirteen pre-programmed and three custom regimens for NMES, TENS, and Pulsed DC Current therapies. In addition to being able to control the treatment duration time, the device can modify waveform type (Symmetrical or Asymmetrical), pulse rates and durations (widths), cycling type, off times, channel ramp times, and on time.

How Electrotherapy Works

The device produces a mild electrical current transmitted via lead wires to electrodes placed on the skin over the motor point of the targeted muscle. Stimulation of motor end plates causes nerve depolarization and activation of muscle fibers, resulting in a muscle contraction.

When applied as a TENS device, electrical stimulation may directly block transmission of pain signals along nerves. In addition, electrical stimulation has been shown to promote the release of endorphins, which are natural painkillers produced by the body.

Empi Continuum Features

The Empi Continuum provides many features that permit a range of treatment options:

- Two independent digital intensity controls
- Timed therapy sessions
- Continuous or cycled stimulation
- Adjustable pulse rates and durations
- 13 pre-programmed with three custom regimens for NMES, TENS, and Pulsed DC Current therapies
- Adjustable ON and OFF time controls

Product Description

Empi Continuum Features (continued)

- Adjustable Ramp Up and Ramp Down time controls
- Dual channel stimulation
- Balanced asymmetrical and symmetrical waveforms
- An accessory output channel allowing use of a remote hand or foot switch for gait training

Indications for Use

As an NMES device, indications are for the following conditions:

- Retarding or preventing disuse atrophy
- Maintaining or increasing range of motion
- Re-educating muscles
- Relaxation of muscle spasms
- Increasing local blood circulation
- Prevention of venous thrombosis of the calf muscles immediately after surgery

As a TENS device, indications are for the following conditions:

- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Relief of pain associated with arthritis

As a Pulsed Current device, indications are for the following conditions:

- Reduction of edema (under negative electrode)
- Reduction of muscle spasm
- Influencing local blood circulation (under negative electrode)
- Retardation or prevention of disuse atrophy
- Facilitation of voluntary motor function
- Maintenance of increase of range of motion

As a functional electrical stimulation (FES) device, the indications for the following condition:

- Stimulation of the leg and ankle muscles of partially paralyzed patients to provide flexation of the foot, thus improving the patient's gait

Product Description

℞ **CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician (or licensed practitioner).

⚠ Contraindications

Empi Continuum should not be used for the following situations or patients with:

- Demand type implanted pacemaker of defibrillator
- Any transcerebral electrode placement
- Any electrode placement that applies current to the carotid sinus region

Specific to use of Empi Continuum as a TENS device:

- Whenever pain syndromes are undiagnosed, until etiology is established

Specific to use of Empi Continuum as an FES device:

- Assisting paraplegic patients into the standing position

⚠ Warnings

Supervised Use – This device should only be operated under the prescription and supervision of a physician (or licensed practitioner) that is familiar with the precautionary measures and operational functions associated with the unit being used.

Long Term Effects – The long term effects of chronic use of electrical stimulation are unknown. Electrical stimulation devices do not have any curative value.

Symptomatic Treatment – This device is a symptomatic treatment and, as such, suppresses the sensation of pain, which would otherwise serve as a protective mechanism.

Central Origin Pain – Electrical Stimulation is not effective for central origin pain such as headaches.

Pregnancy – The safety of using electrical stimulation during pregnancy or birth has not been established.

Throat Stimulation – Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrodes are placed across the throat or mouth. This may be strong enough to close off the airway or cause breathing difficulty.

Transthoracic Stimulation – Do not apply electrical stimulation transthoracically (through the chest area) in that the introduction of electrical current into the heart may cause cardiac arrhythmias.

Skin & Vascular Problems – Do not use this device over swollen, inflamed or infected areas, skin eruptions, or areas of decreased sensation.

Heart Disease – Precaution should be taken prior to using electrical stimulation on patients suspected of having heart disease.

MRI Scans – Do not wear electrode or controller during Magnetic Resonance Imaging (MRI) scans as this may result in metal overheating and causing skin burns in the area of the patch.

Warnings (continued)

Tripping – Care should be used to avoid tripping on lead wires, especially when the foot switch is utilized.

High Frequency Surgical Devices – Simultaneous connection of a patient to a high frequency surgical device may result in burns at the site of the electrodes and possible damage to the device.

Damage From Liquids – Do not immerse the device in water or other liquids. Water or liquids could cause malfunction of internal components of the system, causing a risk of injury to the patient.

Electrical Shock – To prevent electrical shock, disconnect the unit from the power source before attempting any maintenance procedures.

Uncomfortable Stimulation – If the stimulation levels are uncomfortable or become uncomfortable, reduce the intensity to a comfortable level. Contact your clinician if the problem persists.

Skin Reactions – On rare occasions, therapy can result in transient skin reactions such as rash, inflammation, irritation, or burns. These skin reactions may be the result of individual sensitivity to the condition of the skin at the onset of treatment, reaction to the materials in the electrodes, or a poor connection between the electrodes and the patient's skin. Advise the patient of this possibility before starting treatment. If a visible skin reaction does occur, instruct the patient to discontinue the treatment and consult the prescribing physician or licensed practitioner.

Lead Connection – Do not connect the lead wires to an AC power source or other equipment not specified as safe for the lead wires. Doing so could result in severe shock or burns whether or not the lead wires are attached to the stimulator.

Electromagnetic Compatibility – Care must be taken when operating this device adjacent to or stacked with other equipment. Potential electromagnetic or other interference could occur to this or other equipment. Try to minimize this interference by not using other equipment in conjunction with it. (i.e. cell phone, etc.). The Empi Continuum should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the Empi Continuum should be observed to verify normal operation in the configuration in which it will be used.

Accessories – Use only accessories that are specifically designed for this device. Do not use the accessories manufactured by other companies on this device. Empi is not responsible for any consequence resulting from using products manufactured by other companies. The use of Accessories, transducers, or cables other than those specified by the manufacturer, may result in increased emissions or decreased immunity of the Empi Continuum.

Warnings (continued)

Defibrillation Signals – Remove the electrodes before defibrillation signals are applied. Defibrillation of a person wearing a device can damage the device whether it is turned on or off. Under some circumstances, there can be risk of burns under the electrode sites during the defibrillation.

Safety – The safety and efficacy of the Empi Continuum system depends on the proper use and handling of the device and accessories. If used improperly, the Empi Continuum has a potentially hazardous electrical output. It must be used only as prescribed. Electrode or lead wire burns may result from misuse. Electrodes and lead wires should be securely fastened to prevent disconnection. The length of lead wires could result in injury. Electrodes and lead wires will eventually wear out. Check accessories regularly for signs of wear and replace if needed.

Proper Electrode Size – Output current density is related to electrode size. Improper application may result in patient injury. If any question arises as to the proper electrode size, consult a licensed practitioner prior to therapy session.

DC Component - The Empi Continuum waveforms may contain a DC component. Always use Empi electrodes with a minimum active area of 16 cm^2 (including Empi square (2″ x 2″) StimCare electrodes). Use of an electrode with an area less than 16 cm^2 can cause burns when the unit is used at higher intensities. Consult your clinician prior to using any electrode less than 16 cm^2.

To calculate this DC component, use the following equation:

$$\text{Measured } V_{(peak)} \times \text{DC Component Percentage}$$

Precautions

Heart Problems – Use caution for patients with suspected or diagnosed heart problems.

Epilepsy – Use caution for patients with suspected or diagnosed epilepsy when using this device.

Hemorrhages – Use caution when there is a tendency to hemorrhage, such as following acute trauma or fracture.

Post Surgical Use – Use caution following recent surgical procedures when muscle contraction may disrupt the healing process.

Uterus – Do not use electrical stimulation over menstruating or pregnant uterus.

Sensory Loss – Do not use electrical stimulation where sensory nerve damage is present, causing a loss of normal skin sensation.

Precautions (continued)

Unequal Electrode Size – Use precaution and follow clinician instructions when using different size electrodes together. Improper use can cause skin irritation or increased stimulation intensity under the smaller electrode.

Prescription – Use electrical stimulation only in the prescribed manner and for the prescribed diagnosis. If there are any changes in the existing condition, or if a new condition develops, the patient should consult a physician.

Effectiveness – Effectiveness is highly dependent upon patient selection by a clinician qualified in the management of pain or rehabilitation.

Keep Out Of Reach Of Children – Keep this device out of the reach of children. If the patient is a child, make sure the child is properly supervised during electrical stimulation.

Leads and Electrodes – Use the device with only the leads and electrodes provided for use by the manufacturer. The safety of other products has not been established, and their use could result in injury to the patient. Use only the electrode placements and stimulation settings prescribed by your practitioner.

Electronic Equipment – Electronic monitoring equipment (such as ECG and ECG alarms) may not operate properly when electrical stimulation is in use.

Microwave or Frequency Sources – Operation in close proximity, such as 3 feet (1 meter), to shortwave or microwave therapy equipment may produce instability in the device output and may shut the device off.

Machinery Operation – Patient should never operate potentially dangerous machinery such as power saws, automobiles, etc. during electrical stimulation.

Flammable – Do not use the device in an environment where flammable or explosive fumes may exist.

External Use – This device is for external use only.

Electromagnetic Energy – Do not operate this device in an environment where other devices are being used that intentionally radiates electromagnetic energy in an unshielded manner. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

Sharp Objects – Do not use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the control panel.

Cables and Connectors – Inspect cables and connectors before each use.

Treatment Outcome – Treatment outcome will be influenced by the patient's psychological state and use of drugs.

Precautions (continued)

Negative Reaction to Stimulation – Patients who react negatively to the stimulation sensation after an adequate trial period or who find stimulation intolerable should not undergo further treatment.

Operation Conditions – This unit should be operated in temperatures between 50 °F and 104 °F (10 °C and 40 °C), atmospheric pressures between 50 and 106 kPa, and relative humidity between 30% and 75%.

Transportation & Storage Conditions – This unit should be transported and stored in temperatures between -40 °F and 158 °F (-40 °C and 70 °C), atmospheric pressures between 50 and 106 kPa and relative humidity between 10% and 90%.

Batteries – Remove the Empi Continuum system batteries if the unit is to be unused for an extended period of time, i.e. 2 weeks or more.

Transportation of Batteries – Do not carry batteries in a pocket, purse or any other place where the terminals could become short-circuited, e.g. by way of paper clip. Intense heat could be generated and injury may result.

Using Device While Sleeping – Do not use while sleeping because the lead wires or the electrodes may become disconnected.

Heat and Cold Products – The use of heat or cold producing devices, such as electric heating blankets, heating pads or ice packs, may impair performance of the electrode or alter the patient's circulation/sensitivity and increase the risk of injury to the patient.

Battery Charger – Only the prescribed Empi battery charger should be used with the Empi rechargeable batteries. Do not attempt to recharge any battery other than the rechargeable battery supplied by Empi for this device. Attempts to charge alkaline or other non-rechargeable batteries could cause the battery to overheat, burst or be permanently damaged.

Radio Frequency Generation – This equipment generates, uses and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interferences to other devices in the vicinity. However, there is no guarantee that the interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning the unit on and off. Try to correct the interference using one or more of the following: reorient or relocate the receiving device, increase the separation between the equipment and consult the Empi Service Department for help.

EMC Information - Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Product Description

Dangers

Electrodes - Any Empi Electrode with a minimum active area of 16 cm^2 may be used with this device. This includes Empi square (2" x 2"), and StimCare Carbon FM. Use of an electrode with an area less than 16 cm^2 can cause burns when the unit is used at higher intensities. Consult your clinician prior to using any electrode less than 16 cm^2.

Dangerous voltage – Stimulus delivered by the TENS waveforms of this device, in certain configurations, will deliver a charge of up to 20 microcoulombs (µC) or greater per pulse and may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax because it may cause a cardiac arrhythmia.

Biohazardous materials – Handle, clean and dispose of components and accessories that have come in contact with bodily fluids according to National, Local and Facility rules, regulations and procedures.

Adverse Effects

Skin irritation, inflammation, and electrode burns beneath the electrodes are potential adverse reactions.

Glossary of Terms

The following symbols may be located on the Continuum stimulator or packaging:

Dangerous voltage – Stimulus delivered by the TENS waveforms of this device, in certain configurations, will deliver a charge of up to 20 microcoulombs (µC) or greater per pulse and may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax because it may cause a cardiac arrhythmia.

Refer to Instruction Manual/Booklet.

Keep Dry

Type BF Applied Part

Manufacturer

Reference Number

Lead wires comply with the Performance Standard for electrode lead wires (21 CFR part 898)

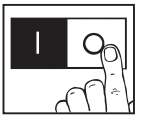
ETL Classified C US, 9900900, Electronic Testing Lab, indicates product meets US and Canadian product safety standards. This device complies with UL Std. 60601-1 and is certified to CAN/CSA Std. C22.2 No. 601.1.

Council Directive 2002/96/EC concerning Waste Electrical and Electronic Equipment (WEEE). Indicates a requirement not to dispose of WEEE as municipal waste. Contact your local distributor for information regarding disposal of the unit and accessories.

ON/OFF

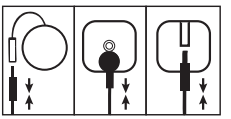
Directions for Use (Patient)

Electrode Setup

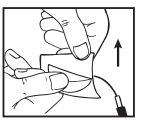


1. Make sure unit is turned off and lead wires are disconnected before and after treatment.

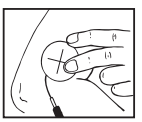
2. Clean electrode application area with soap and water. Rinse and dry. Electrode should only be applied to intact, clean skin (e.g., not over open wounds, lesions, infected, or inflamed areas).



3. With electrodes still on liner, connect lead wire from unit electrode connector. No bare metal should be visible.

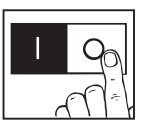


4. Remove electrode from liner by grasping the edge of the electrode and peeling it off the liner. Retain liner for storage.

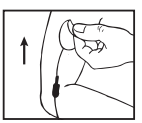


5. Place the electrode on exact skin location by applying the center of the electrode first and smoothing down to electrode edges.

6. Attach lead wire to unit and begin treatment.



7. After treatment, turn unit off.



8. Remove electrode from skin by peeling electrode edge.

Electrode Setup (continued)

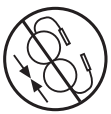
Precautions

9. DO NOT place electrodes on broken skin. If skin irritation develops, discontinue use. Consult physician. Replace electrodes when they do not adhere or when treatment becomes uncomfortable.

10. DO NOT use unit while driving or operating machinery.

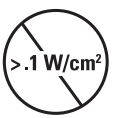
11. For single patient use only. These electrodes may be repositioned up to several times on the same patient.

12. Stimulation should not be applied to transcerebrally or over the anterior neck region.



13. Keep electrodes separated during treatment.

14. DO NOT remove electrode by pulling on the lead wire.



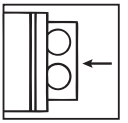
15. DO NOT exceed 0.1 Watts/cm^2.

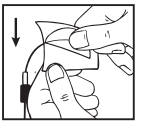
16. Using stimulation electrodes that are too small or incorrectly applied could result in discomfort or skin burns.

Directions for Use (Patient)

Re-Application and Storage of Electrodes

- If adhesive becomes over-saturated, allow electrode to air dry in a refrigerator with adhesive side up until gel regains tack.
- If the electrode gel appears dry, add a few drops of water to the electrode gel. Let rest to regain tack and apply to skin.
- If electrode accumulates dirt/dust in the adhesive, the impedance increases, usually leading to increased heat dissipation at the electrode which can lead to skin burns. Inspect the electrode for dust and dirt accumulation before reuse. Feel the electrode to make sure it is still tacky. If the adhesive has accumulates too much dirt/dust, it will no longer adhere. Replace electrode when it does not adhere.
- Between uses (on the same patient), return electrode to liner and store in resealable bag in a cool place out of direct sunlight.





NOTE: The life of the electrode varies depending on skin conditions, skin preparation, type of stimulation, storage, and climate.

Getting Started

Your kit may include:

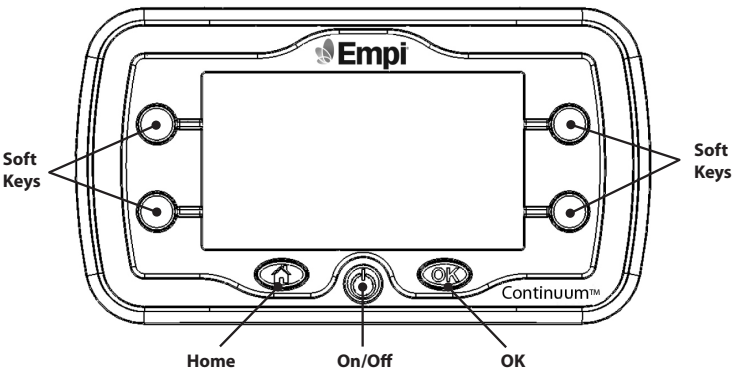
- AA Batteries
- Belt Clip
- Carrying Case
- Electrodes and Touch proof Lead Wires Note: Your electrodes have been specified by your clinician as part of the prescription.
- Empi Continuum Device
- Battery charger and instructions for use
- Instruction Manual

Using the Front Panel

Before you use the device, you should be familiar with the location of the Soft Key control buttons, ON/OFF (⏻) button, OK button and the Home button.

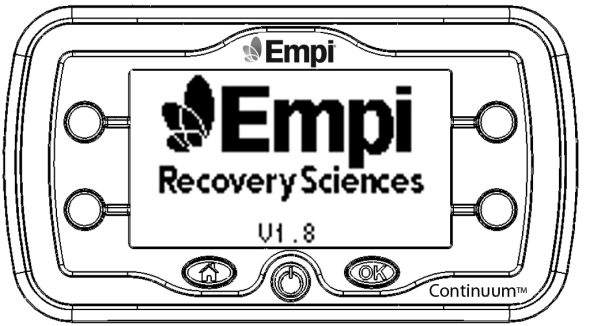
Simple Operational Procedure Steps

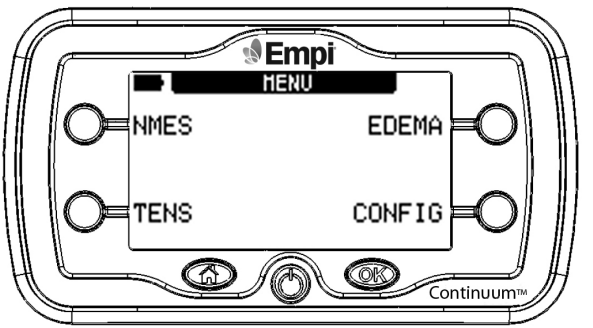
The front panel should appear as shown below.



Using the Front Panel (continued)

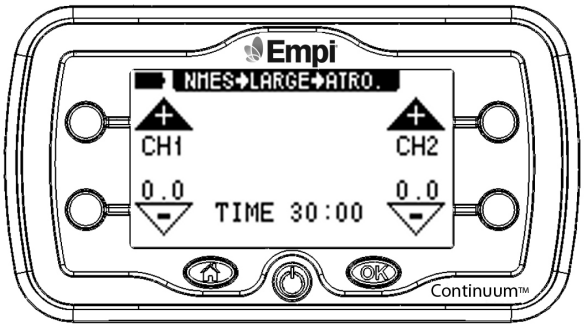
1. Press the ON/ OFF button (⏻) located on the bottom row, middle button. You should first see the Empi logo along with software version number displayed on the LCD for four seconds before displaying a therapy options menu as seen below. The device is now ready to function.





Using the Front Panel (continued)

2. If your unit has previously been configured for operation by a clinician, selecting one of the options (NMES, TENS or Edema) will display the "In-Progress" screen on the LCD as shown below. For instructions on programming your unit, see "Product Information (Clinician)" on page 20. For specific therapy settings, contact your clinician.



3. Press the soft key next to the Channel 1 UP arrow. This will ramp up the level of stimulation for Channel 1. You should see a dot next to the channel output on the LCD screen when output is active.

4. Repeat this procedure for channel 2 on the right if using two channels. You can only ramp intensity on an active channel and can only ramp one channel at a time.

5. If the device has operated as expected, turn it off by pressing the ON/OFF (⏻) button located on the bottom row, middle button.

6. If the LCD does not display any information at startup, check the battery compartment. If the batteries have not been inserted, see the "Changing the Batteries" on page 17. If the batteries have been inserted, change batteries.

7. If after changing batteries, the device still does not respond, refer to the Troubleshooting guide on page 47.

Directions for Use (Patient)

Programming & Adjusting Stimulation

NOTE: The following steps assume that your clinician has set up the device for you. If you are unsure, call your clinician before proceeding. The instructions below describe all of the buttons you should press to work the device. Please note the config button is intended for clinician use.

1. Connect the lead wires to the device. If only one lead wire will be used, plug it into the Channel 1 output channel.

   CAUTION: Ensure the device is OFF before connecting the lead wires.

2. Power on the device by pressing the ON/OFF (⏻) button
3. Press the type of treatment option desired from the main options menu.
4. Select the desired localized treatment type.
5. Select and/or modify the related parameter values for the treatment type and then press OK to lock them in.
6. Begin the treatment by pressing the intensity buttons found to both the left and right of the screen. Press the Up arrows to increase intensity on channel 1 or 2 and press the Down arrows to decrease intensity on channel 1 or 2.
7. Treatment can be ended by pressing the OFF button for at least 1sec.
8. Store electrodes for future use. See instructions on page 12 for electrode storage and maintenance.
9. The Continuum device locks the intensity increase buttons to prevent accidental increases in intensity. This safety feature is activated after 20 seconds of unchanged intensity.
10. To unlock the device, press either intensity Down button. You can now increase the intensity.

Other Features

Changing the Batteries

Change BOTH of the AA batteries when:

- The low battery indicator is visible on the LCD
- The Low Battery message displays
- If the device will not turn on.

Turn off the device to replace batteries. Open the battery door by placing your thumb on the notch and the bottom back side of the unit and pushing up while pulling out. When replacing the batteries, be sure the battery polarity (+ and -) markings match the markings on the device. Use AA alkaline or rechargeable NiMH batteries. The life of the battery is dependent on the program and amplitude (intensity) being used. The battery use indicater may not show 100% power when a fully charged rechargable battery is used; but the battery life is still full.

NOTE: Do not overcharge batteries. Batteries should remain in the charger for the recommended time. Remove the batteries from the charger once charge is complete. See the Instruction for Use for the battery charger for recommended charging time.

To Replace the Battery Cover

1. Insert the small lip at the base of the cover.
2. Insert the top of the cover and press until it clicks securely in place.

Using the Belt Clip

Empi Continuum has a simple belt clip that fits comfortably over a belt or waistband. To attach the belt clip, simply face the back of the device toward you and slide the device, with a gentle pull of the clip tab. When in place, you should feel a slight tension holding it in place.

Using the Kick Stand

Empi Continuum has a simple, pull-out Kick Stand for use in patient monitoring. To use the kick stand, turn the device to the back side. Placing your finger on the recessed tab, pull the stand out for use.

Language: To switch the language of the device:

1. Select "CONFIG" on the Home screen by pressing the lower right-hand soft key
2. Select "SETTINGS" by pressing the upper right-hand soft key
3. Press the lower left-hand soft key once to toggle to the "Language" option
4. Use the right-hand soft keys to select your preferred language
5. Press "OK" on the bottom right

Contrast: To adjust the contrast of the screen:

6. Select "CONFIG" on the Home screen by pressing the lower right-hand soft key
7. Select "SETTINGS" by pressing the upper right-hand soft key
8. The screen will default to the "Contrast" option
9. Use the right-hand soft keys to adjust the contrast as desired
10. Press "OK" on the bottom right

Troubleshooting and Repair

Troubleshooting

If the device does not function:

- Make sure the batteries are properly installed (check polarity markings)
- Make sure the battery contacts are clean.

If the device is ON, but does not respond to pressing the key pad buttons:

- Detach all patient lead wires from the device.
- Remove batteries from the device.
- Wait 10 seconds.
- Re-insert batteries and resume treatment.

If the Low Battery Indicator is visible, replace both batteries.

If the device is on, the indicator lights are illuminated over the intensity controls, and you feel no stimulation, check and verify the connection of lead wires and electrodes.

If the device appears to be functioning, and there is no stimulation, replace the lead wires and/or electrodes.

If the channel shows an "OPEN" error message, check to make sure that all electrodes and lead wires are properly attached. If the message continues to show after all electrodes and wires have been checked, remove the electrodes, clean and dry the skin area under the electrodes, and replace the electrodes. If the error message persists, call Empi Customer Service.

If you are unable to increase the intensity of the device, the device's intensity lock safety feature has likely engaged. To disengage, decrease the channel's intensity. You should then be able to increase the intensity.

For more detailed Troubleshooting information, see "Troubleshooting" on page 47.

Repair

There are no user serviceable parts inside the device. If the device appears to be non-functional, contact your clinician, or contact Empi directly at (800) 862-2343.

Maintenance, Cleaning, and Storage

Maintenance

Under normal conditions, the device does not require periodic maintenance, calibration or testing.

Cleaning

Use a damp cloth with mild soap to clean the exterior of the device and lead wires. Use of other cleaning solutions may damage these items. Never immerse the device in liquids.

Storage

To store the stimulator for an extended time (more than 30 days), remove the batteries and store the device in a cool, dry place.

Product Information (Clinician)

The Empi Continuum is a state-of-the-art NMES system that incorporates three widely used clinical modalities: TENS, NMES, and Pulsed DC Current (Low Volt). The device is designed to allow the clinician to introduce electrotherapy into the rehabilitation cycle earlier than with conventional NMES devices. The NMES component can be used pre-surgically to treat disuse atrophy. The Pulsed DC Current feature can be used pre- or post-surgically to increase local circulation. The numerous NMES regimens are available for muscle re-education when the patient is ready for the post-surgical rehabilitation program. The Empi Continuum may also be used as a TENS for the symptomatic relief and management of chronic, intractable pain and as an adjunctive treatment for post-surgical and post-trauma acute pain.

The Empi Continuum has thirteen pre-programmed and three custom regimens for NMES, TENS, and Pulsed DC Current, each with Empi-recommended default settings. All the clinician needs to do is choose the appropriate therapy for the intended clinical application (see "Pre-programmed & Custom Regimens" on page 22) and the device is ready for use. The clinician can control the patient's access to the treatment parameters by either locking out treatment options altogether or by simply locking out parameter changes.

For treatment flexibility, multiple stimulation parameters are adjustable including:

- 2 Independent Intensity Controls
- Discrete adjustable rate settings
- Adjustable ON and OFF time controls
- Adjustable Ramp Up and Down controls
- Adjustable Treatment duration time
- Stimulation may be synchronous (simultaneous) or asynchronous (alternating)
- Symmetric, or Asymmetric Biphasic waveforms or Pulsed DC waveforms

The device also has the ability for:

- Modifiable LCD Contrast settings
- Four different possible Languages (English, French, Spanish and German)
- Display of unit statistics
- Clearing of Non-Volatile memory to default
- Clearing of Unit Statistics

Hardware and Labeling

External Remote Switch Port

The remote switch acts as a trigger for the selected regimen. There are two available External Remote Switches: Remote Hand Switch and Remote Foot Switch. The remote switches should be used with the custom program. For information on using a remote switch in conjunction with a gait Training Protocol, see page 37. Switches are optional accessories and may not be included.

Front Panel

Soft Key Control

The Soft Keys on the left and right side of the unit serve multiple purposes for this device. The left side soft keys have the ability to scroll modifiable items into or out of view. Additionally, the left side soft keys will act to increase or decrease the intensity of channel 1 output. Similarly, the right side soft keys act as a means of scrolling an item's value up or down. Additionally, the right side soft keys will increase or decrease the intensity of channel 2 output. The stimulation level for each channel can be seen on the LCD screen coincident with the associated soft keys.

ON/OFF Key

The dedicated button with the international ON/OFF (⏻) symbol both powers up and powers down the device.

Home Key

The dedicated button with the picture of a Home on it will serve to transition the unit to the Options menu page.

OK Key

The "OK" key is used as a means of putting the stamp of "locking" in parameter selections and item selections.

Backside Labeling

The labeling, found on the back of the device, details the standards to which this device has been tested (i.e., ETL approval). Federal law (USA) restricts this device to sale by or on the order of a physician.

Pre-Programmed & Custom Regimens

The Empi Continuum has thirteen pre-programmed and three custom regimens. Regimens are the centerpiece of the Empi Continuum. They are designed for very specific clinical applications and are intended to simplify the use of the device by allowing the clinician to educate the patient on the use of the device with very little effort.

The Empi Continuum device categorizes NMES Pre-set and Custom programs by Large Muscle and Small Muscle. An example of Large muscles would be the quadriceps, hamstrings, gluteus maximus and medius, adductor magnus, latissimus dorsi and abdominal musculature. Small muscle examples would be anterior tib, bicep, deltoid, supraspinatus, teres minor, subscapularis, and the intrinsic foot and hand muscles.

NMES Regimens

Large Muscle Atrophy — Summary
This is a sequenced, 2-channel program for strengthening and re-educating large atrophied muscles. All parameters are preset with the exception of Treatment Time, Off Time and the Pulse Rate which can be adjusted by the clinician. The range of adjustments for Treatment Time, Off Time and Pulse Rate are listed in the table below.

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min
Off Time	0-60 sec	30 sec
Pulse Rate	2 Hz-150 Hz	50 Hz

Preset Parameters	Settings
Waveform Type	SYM
Cycling Type	LAG
Pulse Width/Duration	300 µs
Lag Delay	3 sec
CH 1 Ramp+	3 sec
CH 1 On Time	12 sec
CH 1 Ramp–	2 sec
CH 2 Ramp+	2 sec
CH 2 On Time	9 sec
CH 2 Ramp–	1 sec

Large Muscle Spasm — Summary
This is a 2-channel program for relaxing and reducing spasmodic tightness in large muscles. All parameters are preset with the exception of Treatment Time, Off Time and the Pulse Rate, which can be adjusted by the clinician. The range of adjustments for Treatment Time, Off Time and Pulse Rate are listed in the table below.

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min
Off Time	0-60 sec	5 sec
Pulse Rate	2 Hz-150 Hz	80 Hz

Preset Parameters	Settings
Waveform Type	SYM
Cycling Type	SIM
Pulse Width	300 µs
Lag Delay	0 sec
CH 1 Up Time	2 sec
CH 1 On Time	10 sec
CH 1 Down Time	2 sec
CH 2 Up Time	2 sec
CH 2 On Time	10 sec
CH 2 Down Time	2 sec

Large Muscle Trigger-Point — Summary
This treatment option is a 2-channel program for relaxation of muscles in a localized area. All parameters are preset with the exception of Treatment Time, Off Time and Pulse Rate which can be adjusted by the clinician. The range of adjustments for Treatment Time, Off Time and Pulse Rate are listed in the table below

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min
Off Time	0-60 sec	10 sec
Pulse Rate	2 Hz-150 Hz	50 Hz

Large Muscle Trigger-Point — Summary (continued)

Preset Parameters	Settings
Waveform Type	SYM
Cycling Type	SIM
Pulse Width	300 µs
Lag Delay	0 sec
CH 1 Up Time	2 sec
CH 1 On Time	10 sec
CH 1 Down Time	2 sec
CH 2 Up Time	2 sec
CH 2 On Time	10 sec
CH 2 Down Time	2 sec

Large Muscle Custom / Switch — Summary

This option offers similar stimulation as Large Muscle Spasm and Trigger-Point if no external Foot Switch is detected.

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min
Off Time	0-60 sec	30 sec
Pulse Rate	2 Hz-150 Hz	35 Hz
Pulse Width	48 µs-400 µs	300 µs
Waveform Type	SYM, ASY	SYM
Cycling Type	SIM, 1 CH, ALT, LAG	SIM
Lag Delay	0-5 sec	0 sec
CH 1 Ramp+	0-5 sec	2 sec
CH 1 On Time	0-60 sec	10 sec
CH 1 Ramp–	0-5 sec	2 sec
CH 2 Ramp+	0-5 sec	2 sec
CH 2 On Time	0-60 sec	10 sec
CH 2 Ramp–	0-5 sec	2 sec

If used with an external Switch, continuous stimulation is available for gait training protocol. The intensity of each channel is independently adjustable. Waveform, pulse width, and pulse rate parameters have default settings and are the adjustable parameters (within range). Depending on the cycle selected, all parameters may not be adjustable.

Small Muscle Atrophy — Summary
This is a 2-channel program for strengthening and re-educating small atrophied muscles. All parameters are preset with the exception of Treatment Time, Off Time and the Pulse Rate which can be adjusted by the clinician. The range of adjustments for Treatment Time, Off Time and Pulse Rate are listed in the table below.

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min
Off Time	0-60 sec	30 sec
Pulse Rate	2 Hz-150 Hz	35 Hz

Preset Parameters	Settings
Waveform Type	ASY
Cycling Type	SIM
Pulse Width	300 µs
Lag Delay	0 sec
CH 1 Up Time	2 sec
CH 1 On Time	10 sec
CH 1 Down Time	2 sec
CH 2 Up Time	2 sec
CH 2 On Time	10 sec
CH 2 Down Time	2 sec

Small Muscle Spasm — Summary
This is a 2-channel program for relaxing and reducing spasmodic tightness in small muscles. All parameters are preset with the exception of Treatment Time, Off Time and the Pulse Rate, which can be adjusted by the clinician. The range of adjustments for Treatment Time, Off Time and Pulse Rate are listed in the table below.

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min
Off Time	0-60 sec	10 sec
Pulse Rate	2 Hz-150 Hz	80 Hz

Small Muscle Spasm — Summary (continued)

Preset Parameters	Settings
Waveform Type	SYM
Cycling Type	SIM
Pulse Width	300 µs
Lag Delay	0 sec
CH 1 Up Time	2 sec
CH 1 On Time	10 sec
CH 1 Down Time	2 sec
CH 2 Up Time	2 sec
CH 2 On Time	10 sec
CH 2 Down Time	2 sec

Small Muscle Trigger-Point — Summary

This treatment option is a 2-channel program for relaxation of muscles in a localized area. All parameters are preset with the exception of Treatment Time, Off Time and Pulse Rate which can be adjusted by the clinician. The range of adjustments for Treatment Time, Off Time and Pulse Rate are listed in the table below.

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min
Off Time	0-60 sec	10 sec
Pulse Rate	2 Hz-150 Hz	50 Hz

Preset Parameters	Setting
Waveform Type	SYM
Cycling Type	SIM
Pulse Duration	300 µs
Lag Delay	0 sec
CH 1 Up Time	3 sec
CH 1 On Time	10 sec
CH 1 Down Time	2 sec
CH 2 Up Time	3 sec
CH 2 On Time	10 sec
CH 2 Down Time	2 sec

Small Muscle Custom / Remote — Summary
This option offers similar stimulation as Small Muscle Spasm and Trigger-Point if no external Hand Switch is detected.

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min
Off Time	0-60 sec	30 sec
Pulse Rate	2 Hz-150 Hz	35 Hz
Pulse Width	48 µs-400 µs	300 µs
Waveform Type	SYM, ASY	ASY
Cycling Type	SIM, 1 CH, ALT, LAG	SIM
Lag Delay	0-5 sec	0 sec
CH 1 Ramp+	0-5 sec	2 sec
CH 1 On Time	0-60 sec	10 sec
CH 1 Ramp–	0-5 sec	2 sec
CH 2 Ramp+	0-5 sec	2 sec
CH 2 On Time	0-60 sec	10 sec
CH 2 Ramp–	0-5 sec	2 sec

If used with an external Switch, continuous stimulation is available for gait training protocol. The intensity of each channel is independently adjustable. Waveform, pulse width, and pulse rate parameters have default settings and are the adjustable parameters (within range). Depending on the cycle selected, all parameters may not be adjustable.

TENS Regimens

TENS Knee — Summary
This treatment option is a 2-channel Modulated Amplitude program for the management of acute or chronic pain control in the knee. All parameters are preset with the exception of Treatment Time and the Pulse Rate, which can be adjusted by the clinician.

Adjustable Parameters	Range	Default
Treatment Time	5-60 min or Continuous	30 min
Pulse Rate	2 Hz-150 Hz	100 Hz

Preset Parameters	Settings
Cycling Time	12 sec
Attenuated Span	40%
Pulse Width	300 µs
Mode	MOD

TENS Shoulder — Summary

This treatment option is a 2-channel Simple Modulated Pulse (SMP) program for the management of acute or chronic pain control in the shoulder. This treatment option modulates the pulse rate and the pulse width at the same time. All parameters are preset with the exception of Treatment time and the Pulse Rate , which can be adjusted by the clinician.

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min
Pulse Rate	2 Hz-150 Hz	100 Hz

Preset Parameters	Settings
Cycling Time	12 sec
Pulse Width	300 µs
Mode	SMP

TENS Back — Summary

This treatment option is a 2-channel Modulated Amplitude program for the management of acute or chronic pain control in the Back. All parameters are preset with the exception of Treatment time and the Pulse Rate, which can be adjusted by the clinician.

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min
Pulse Rate	2 Hz-150 Hz	100 Hz

Preset Parameters	Settings
Cycling Time	12 sec
Span	40%
Pulse Width	300 µs
Mode	MOD

TENS Hand — Summary

This treatment option is a 2-channel Simple Modulated Pulse (SMP) program for the management of acute or chronic pain control in the hand. This treatment option modulates the pulse rate and the pulse width at the same time. All parameters are preset with the exception of Treatment Time and the Pulse Rate , which can be adjusted by the clinician.

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min
Pulse Rate	2 Hz-150 Hz	100 Hz

Preset Parameters	Settings
Cycling Time	12 sec
Pulse Width	300 µs
Mode	SMP

TENS Foot — Summary

This treatment option is a 2-channel Simple Modulated Pulse (SMP) program for the management of acute or chronic pain control in the foot. This treatment option modulates the pulse rate and the pulse width at the same time. All parameters are preset with the exception of Treatment Time and the Pulse Rate , which can be adjusted by the clinician.

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min
Pulse Rate	2 Hz-150 Hz	100 Hz

Preset Parameters	Settings
Cycling Time	12 sec
Pulse Width	300 µs
Mode	SMP

TENS Custom — Summary
This treatment option is a sequenced, 2-channel Modulated Amplitude (MOD) or a Simple Modulated Pulse (SMP) program for the management of acute or chronic pain. All parameters have default settings and are adjustable by the clinician within the range described in the table below.

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min
Pulse Rate	2 Hz-150 Hz	100 Hz
Cycling Time	3-20 sec	12 sec
Span (MOD Only)	20% - 95%	40%
Mode	SMP, MOD	SMP

Preset Parameters	Settings
Pulse Width	300 µs

Pulsed DC Current Regimens

Pulsed DC Current (Edema) Acute — Summary
This treatment option is a sequenced, positively DC unbalanced (+) 2-channel program for edema reduction and increased circulation. All parameters are preset with the exception of Treatment time, which can be adjusted by the clinician.

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min

Pulsed DC Current (Edema) Chronic — Summary
This treatment option is a sequenced, positively DC unbalanced (-) 2-channel program for edema reduction and increased circulation. All parameters are preset with the exception of Treatment time, which can be adjusted by the clinician.

Adjustable Parameters	Range	Default Setting
Treatment Time	5-60 min or Continuous	30 min

NMES Regimens

NMES large muscle:

- Amplitude at 1000 ohm is 100 V_{peak} (DC component 2.2%)
- Amplitude at 500 ohm is 50 V_{peak} (DC component 3.4%)

NMES small muscle:

- Amplitude at 1000 ohm is 100 V_{peak} (DC component 2.1%)
- Amplitude at 500 ohm is 50 V_{peak} (DC component 4.3%)

TENS Regimens

TENS SMP:

- Amplitude at 1000 ohm is 100 V_{peak} (DC component 2%)
- Amplitude at 500 ohm is 50 V_{peak} (DC component 3.4%)

TENS MOD:

- Amplitude at 1000 ohm is 100 V_{peak} (DC component 2.3%)
- Amplitude at 500 ohm is 50 V_{peak} (DC component 3.4%)

Pulsed DC Current Regimens

Acute Bi-Phasic:

- Amplitude at 1000 ohm is 100 V_{peak} (DC component 1.6%)
- Amplitude at 500 ohm is 50 V_{peak} (DC component 2.7%)

Acute Tri-Phasic:

- Amplitude at 1000 ohm is 100 V_{peak} (DC component 2.3%)
- Amplitude at 500 ohm is 50 V_{peak} (DC component 3.1%)

Chronic Bi-Phasic:

- Amplitude at 1000 ohm is 100 V_{peak} (DC component 2%)
- Amplitude at 500 ohm is 50 V_{peak} (DC component 3.7%)

Programming the Device

Setting Treatment Parameters

Programming the Empi Continuum is designed to be intuitive. The Empi Continuum has been engineered to guide the clinician through the programming process. The clinician will first set up the parameters for treatment and then proceed to restrict the user's ability to reprogram the unit. In essence, the clinician will set up the device such that the user has only to press one button before starting the treatment.

NMES Parameters

1. Power ON the device by depressing the ON/OFF (⏻) button.
2. Press the top soft key on the left to select "NMES" programming.
3. Select the Muscle Type – either Large or Small Muscle.
4. Select Treatment type – Atrophy, Spasm, Point, or Custom.
5. Using left side soft key, scroll to the desired parameter item.
6. Using right side soft keys, scroll parameter value up or down.
7. Press the Home button to get back to the Option menu.
8. Press the soft key labeled "CONFIG."
9. Press right side soft key labeled "LOCKS."
10. Using left soft keys, scroll to desired item "NMES L.MUSCLES" or "NMES S.MUSCLES."
11. Press the upper right soft key until a locked icon displays.
12. Press Home button to accept the change.
13. Press the "NMES" button, a lock must be visible beside the previously selected item ("LARGE MUSCLE" or "SMALL MUSCLE").
14. Select the locked treatment to go to the "In-Progress" screen.
15. Set up patient with electrodes and ramp-up intensity.

TENS Parameters

1. Power ON the device by pressing the ON/OFF (⏻) button.
2. Press bottom soft key on the left to select TENS programming.
3. Select the body part by scrolling thru options and press "OK."
4. Using left side soft key, scroll to the desired parameter item.
5. Using right side soft keys, scroll parameter value up or down.
6. Press the Home button to get back to the Option menu.
7. Press soft key labeled "CONFIG."
8. Press right side soft key labeled "LOCKS."
9. Using lower left soft key, scroll to item "TENS."
10. Press the upper right soft key until a locked icon displays.

11. Press Home button to accept the change.

12. Press the "TENS" button (a lock must be visible beside it) to go to the "In-Progress" screen.

13. Set up patient with electrodes and ramp up the intensity.

Pulsed DC Current (Edema) Parameters

1. Power ON the device by pressing the ON/OFF (⏻) button

2. Press top soft key on right to select EDEMA programming.

3. Select Treatment type – Acute or Chronic.

4. Using right side soft keys, scroll parameter value up or down

5. Press the Home button to get back to the Option menu.

6. Press soft key labeled "CONFIG."

7. Press right side soft key labeled "LOCKS."

8. Using lower left soft key, scroll to item "EDEMA."

9. Press the upper right soft key until a locked icon displays.

10. Press Home button to accept the change.

11. Press the "EDEMA" button (a lock must be visible beside it) to go to the "In-Progress" screen.

12. Set up patient with electrodes and ramp up the intensity.

Locking the Device

The Empi Continuum has been designed with a feature that allows the clinician to set up a treatment regimen for each of the three different stimulation therapy type programs. This feature allows the clinician to be confident that the treatment instructions are more likely to be followed by the patient during the course of treatment. After having set up a treatment's parameters, the clinician can do as follows:

1. On the main options page, press "CONFIG" to get to the CONFIG menu.

2. Press "LOCKS" (Lower Right Soft Key).

3. Using the Left Soft Keys, scroll through available items (NMES L.MUSCLES, NMES S.MUSCLES, TENS and EDEMA). Initially, these items will show an unlock icon to the right on the LCD screen.

4. For each item, press the upper right hand soft key once. This will show the lock icon, an image of a closed pad lock.

5. Press the Home key.

6. Notice the small lock beside the treatment option that was previously locked. Notice also that when the corresponding soft key is pressed, user transitions directly to the In-Progress screen.

This can be done for all treatment types.

Additional Lockout Feature

There is an additional lockout feature that the clinician can use to remove the option of a treatment from the screen so that the patient does not have the option of selecting a particular treatment type. It can be accomplished as follows:

1. On the main options page, press "CONFIG" to get to the CONFIG menu
2. Press "LOCKS" (Lower Right Soft Key).
3. Using the Left Soft Keys, scroll down to one of the four lock items (NMES L.MUSCLES, NMES S.MUSCLES, TENS and EDEMA). Then, using the upper right hand soft key, scroll until a forbidden icon is shown.
4. Press the "Home" button to get back to the main menu. Notice that the therapy option has been removed from the display.

Unlocking the Device

When the Empi Continuum is locked, it allows the clinician to control the patient's use of the device to assure access to only the pre-selected protocol. "Unlocking" the device gives the clinician the ability to set up a new treatment protocol. To "unlock" the device, perform the following steps:

1. Press the ON button to turn on the device, or press the Home button.
2. Once the main Options menu is displayed, choose "CONFIG" option.
3. Choose the "LOCKS" option.
4. Using the Left Soft Keys, scroll down to a lock items (NMES L.MUSCLES, NMES S.MUSCLES, TENS and EDEMA).
5. Use the lower right side soft key to scroll the item's value until an "unlock" icon is shown.
6. Press the Home button to return to the main menu.

View & Reset Compliance Data

The Empi Continuum monitors patient usage of the device. This feature helps determine patient compliance with the selected protocol(s). The following information is collected:

- Number of total sessions
- Total session time (hours)
- Average session time (minutes)
- Average Channel 1 Intensity
- Average Channel 2 Intensity

To View the aforementioned Compliance Data, the following steps are to be applied:

1. Press the ON button to turn on the device.
2. Once the main Options menu is displayed, choose "CONFIG" option.
3. Choose the "data" option (upper right soft key).
4. Use the left side soft keys to scroll through the data.

After scrolling through the data, the clinician can choose to erase (reset) the data for future collection of compliance data. Compliance Data is captured in 5 minute increments when the unit is producing output waveforms. When the Clinician needs to reset this compliance data due to a new patient, follow the following steps:

1. Press the ON button to turn on the device.
2. Once the main Options menu is displayed, choose "CONFIG" option.
3. Choose the CLEAR option.
4. To clear Compliance data, select "DATA" option.
5. Press the Home button.

Resetting Parameter Defaults

The Empi Continuum has the ability to modify treatment parameters prior to treatment application. This allows the clinician to tailor treatment to the individual patient. When the clinician needs to reset this data due to a new patient, the following steps are to be applied:

1. Press the ON button to turn on the device.
2. Once the main Options menu is displayed, choose "CONFIG" option.
3. Choose the "CLEAR" option.
4. To reset the waveform data to parameter default values, select the "PARAMETER" option.

Choosing a Language

The Empi Continuum has the ability to modify the language displayed upon the LCD screen. The options are English (Default), French, Spanish and German. When the clinician needs to alter the currently displayed language, the following steps are to be applied:

1. Press the ON button to turn on the device.
2. Once the main Options menu is displayed, choose "CONFIG" option.
3. Choose the "SETTINGS" option.
4. Use the lower left soft key to scroll to the "Languages" option.
5. Use the right side soft keys to scroll to the proper language.
6. Press the OK button to select the language.
7. Press the Home button.

Changing the Contrast

The Empi Continuum has the ability to modify the contrast setting of the LCD screen to immediately fit the needs of the patient or the clinician. When the clinician needs to alter the contrast of the unit, the following steps are to be applied:

1. Press the ON button to turn on the device.
2. Once the main Options menu is displayed, choose "CONFIG" option.
3. Choose the "SETTINGS" option.
4. Use the right side soft keys to scroll to the "Contrast" setting to where it needs to be.

Changing the Switch Working Mode

The EMPI Continuum has the ability to modify the working mode of an attached Hand or Foot switch. Available options are "Simultaneous" or "Alternated".

- In "Simutaneous" mode, both channel 1 and 2 will work simultaneously.
- In "Alternated" mode, channel 1 and 2 will work alternately

To access this setting, the following steps are to be applied:

1. Press the ON button to turn on the device.
2. Once the main Options menu is displayed, choose "CONFIG" option.
3. Choose the "SETTINGS" option.
4. Use the lower left soft key to scroll to the "SWITCH" option.
5. Use the right side soft keys to select the switch working mode
6. Press the home screen button.
7. Notice that if a switch is plugged in, an icon will be shown in the upper right corner of the display.

Using the Foot Switch

The Empi Continuum unit has the ability to use a foot switch for gait training. The Foot Switch must be plugged in so that the unit recognizes that a gait treatment is wanted. Otherwise, a normal Large Muscle, Custom treatment is performed. To do this, the following steps are to be applied:

1. Press the ON button to turn on the device.
2. Once the main Options menu is displayed, choose the NMES option.
3. Choose the "LARGE MUSCLE" option.
4. Choose the "CUSTOM" option.
5. Modify adjustable regimen parameters as needed and then press the "OK" button.
6. Plug the Foot Switch into the remote jack in the unit.
7. Increase intensity. For Channel 1, the unit will output a waveform as the foot is lifted up, and stop its output as the foot is down. For Channel 2, the output will behave according to the selected switch working mode.

Using the Hand Switch

The Empi Continuum unit has the ability to use a hand switch for user-activated stimulation. The Hand Switch must be plugged in so that the unit recognizes that gait treatment is wanted. Otherwise, a normal Small Muscle, Custom treatment is performed. To do this, the following steps are to be applied:

1. Press the ON button to turn on the device.
2. Once the main Options menu is displayed, choose the NMES option.
3. Choose the "SMALL MUSCLE" option.
4. Choose the "CUSTOM" option.
5. Modify regimen parameters as needed and then press the "OK" button.
6. Plug the Hand Switch into the remote jack in the unit.
7. Increase intensity. For Channel 1, the unit will output a waveform as the hand switch is pressed, and stop its output as the hand switch is depressed. For Channel 2, the output will behave according to the selected switch working mode.

Both switches should be used with the custom programs, not with the pre-set therapies.

Product Information (Clinician)

Accessories

Battery
Two AA rechargeable NiMH Batteries (Part Number: 200034-001)

Electrodes
Any Empi Electrode with a minimum active area of 16 cm^2 may be used with this device. This includes Empi square (2″ x 2″) StimCare electrodes.

DANGER: Use of an electrode with an area less than 16 cm^2 can cause burns when the unit is used at higher intensities. Consult your clinician prior to using any electrode less than 16 cm^2.

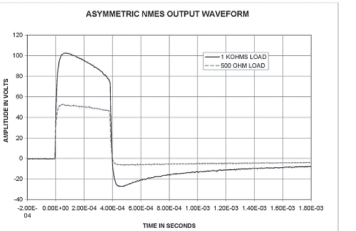
Lead Wires
Any Empi TENS/NMES Lead Wire (100 cm – 40″) with the touch proof device connection (part number 193057-100).

Remote Switches
- Use either: Empi Foot Switch - Part Number: 198887-001
- Empi Hand Switch - Part Number: 57202241
- Bifurcated Lead wire (for Edema) - Part Number - 700211-001
- Dispersive Pad (for Edema) - Part Number - 199501-001

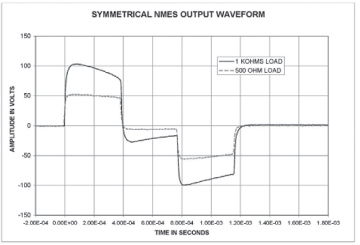
Technical Data

Standard Measurement Conditions
- Temperature - 25°C +/-5°C
- Load -1 kohm
- Power Supply - 3.0V DC +/- 10%

Typical Waveforms
The following are theoretical standard measurement output voltage across purely resistive loads at maximum intensity setting. Pulse Width and Vpp measured as shown across 500 ohm and 1k ohm loads. Your output may vary depending on parameter settings.

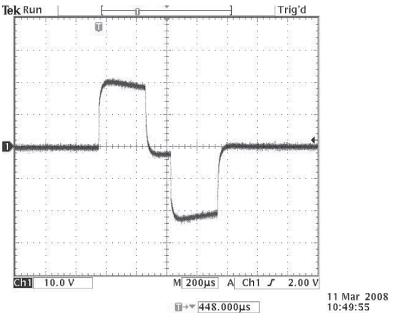


Typical Waveforms (continued)

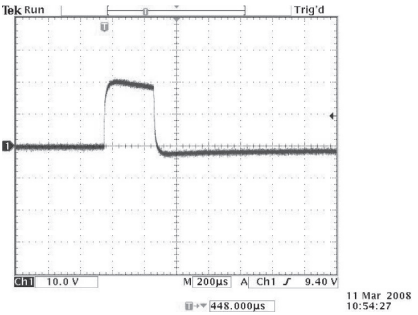


Output Waveforms

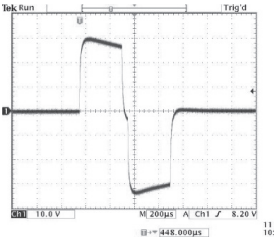
NMES Symmetrical Waveform

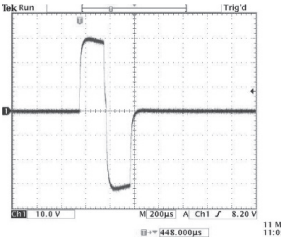


NMES Asymmetrical Waveform

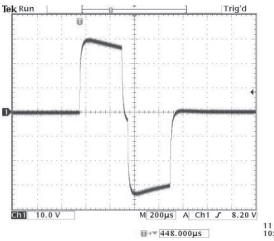


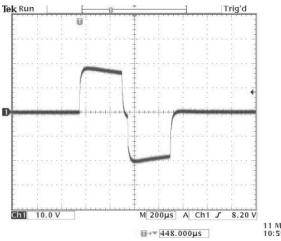
TENS Shoulder High / Low Cycle SMP Waveform



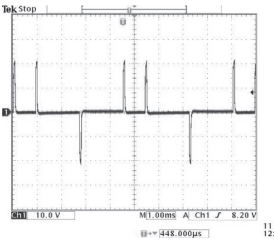


TENS Knee Modulated Amplitude Full / Partial Waveform

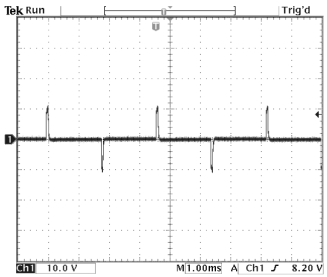




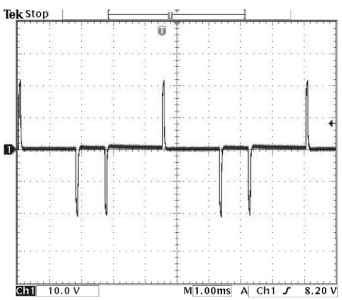
Pulsed DC Current Acute Tri-Phasic Waveform
Pulse Rate 208 Hz



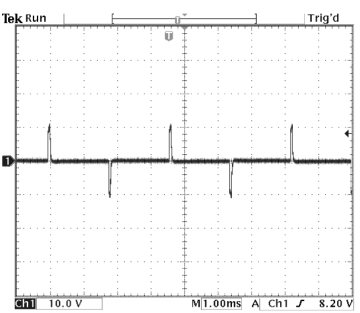
Pulsed DC Current Acute Bi-Phasic Waveform
Pulse Rate 270 Hz



Pulsed DC Current Chronic Tri-Phasic Waveform
Pulse Rate 208 Hz



Pulsed DC Current Chronic Bi-Phasic Waveform
Pulse Rate 270 Hz



Product Information (Clinician)

Timer

The timer is adjustable 5 to 60 minutes or unlimited.

Remote Control Hand Switch

Active regimen starts with closed contact.

Low Voltage Indication

- Indicator Threshold: 2.07 Volts (typical)
- Shutdown Voltage: 1.77 Volts (typical) 1.5 Volt Minimum

*These voltages may be tested under NO load condition.

Physical Characteristics

- Size: 1.26″ (3.2cm) x 3.3″ (8.4cm) c 4.5″ (11.4)
- Weight (with batteries): 226.8 grams

Environmental Conditions

- Operational Temperature: 10° C to 40° C
- Humidity (Maximum): 10% - 90% RH
- Transport & Storage: Store in Dry, Cool Place 40° C to 70° C
- Pressure: 50-106 kPA

EN 60601-1 Classification

Type BF Applied Part

- Internally powered only
- Ordinary protection ingress of liquids
- Continuous operation
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Guidance and Manufacturer's Declaration–Electromagnetic Emissions

The Empi Continuum is intended for use in the electromagnetic environment specified in the table below. The user of the Empi Continuum should assure that it is used in such an environment.

Emission Tests	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Empi Continuum uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The Empi Continuumt is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A - Battery Operated Device	
Voltage fluctuations/ Flicker Emissions IEC 61000-3-3	N/A - Battery Operated Device	

Guidance and Manufacturer's Declaration–Electromagnetic Immunity

The Empi Continuum is intended for use in the electromagnetic environment specified in the table below. The user of the Empi Continuum should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not Applicable- Battery Operated Device	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable- Battery Operated Device	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not Applicable- Battery Operated Device	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Empi Continuum requires continued operation during power mains interruptions, it is recommended that the Empi Continuum be powered from an uninterrupted power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration–Electromagnetic Immunity (continued)

The Empi Continuum is intended for use in the electromagnetic environment specified in the table below. The user of the Empi Continuum should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Empi Continuum, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = \frac{[3.5]}{3}\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \frac{[3.5]}{3}\sqrt{P}$ 80 MHz to 800 MHz $d = \frac{[7]}{3}\sqrt{P}$ 800 MHz to 2.5 GHz
			where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Empi Continuum is used exceeds the applicable RF compliance level above, the Empi Continuum should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Empi Continuum.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Empi Continuum

The Empi Continuum is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Empi Continuum can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Empi Continuum as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter m	
	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Troubleshooting

Problem	Possible Cause	Solution
Display does not come on	Battery	**A.** Try fresh batteries **B.** Try 2 AA Energizer or Eveready alkaline batteries. **C.** Ensure batteries are inserted correctly. See instructions for proper placement.
	Battery Contact Failure	**A.** Check contacts are in place. **B.** Check contacts are not broken. **C.** Check contacts are not pushed in. They should make contact when inserted.
Weak Stimulation with fresh batteries	Electrodes Dried Out	Replace electrodes
	Electrode Placement	Make certain Electrodes are at least 2" apart.
Stimulation stops with fresh batteries	**A.** Lead Wires are Old, Worn or Damaged **B.** Bad electrode Contact	**A.** Replace. **B.** Reapply electrodes securely & firmly. **C.** Make certain Electrodes are at least 2" apart.
	Damaged, Worn Electrodes or Lead Wires	Replace
Stimulation weakens within minutes of start of treatment with fresh batteries	This is a Normal body adaptive process	Increase the intensity
Stimulation Uncomfortable	Amplitude too High	Decrease Intensity
	Electrodes too close	Reposition electrodes to be a minimum of 2 inches apart.
Stimulation Ineffective	Damaged/Worn Electrodes or Lead Wires	Replace
	A. Ensure the proper regimen is being used. **B.** Improper Electrode placement.	**A.** Refer to "Preprogrammed & Custom Regimens" on page 22 for regimen descriptions. **B.** Contact clinician if discomfort persists. **C.** Reposition electrodes.
	Unknown	Contact clinician.
Stimulation only felt on one electrode	Low Battery	Replace or Recharge Batteries
	Improper Placement of Electrode	**A.** Reposition electrodes to be a minimum of 2 inches apart. **B.** Replace Electrodes
Stimulation on one channel (side) only.	**A.** Worn or Damaged Electrode **B.** Improper Electrode placement.	**A.** Reposition electrodes to be a minimum of 2 inches apart. **B.** Replace Electrodes
	Worn/Damaged Lead Wires	Replace
	Lead Wire Component Failure	Try each lead wire independently in each channel. If there is no output on either channel, the lead wire is defective and should be replaced. If there is an output on one channel, a component may have failed. Call the repair department.
Intermittent Output	Lead Wires	**A.** Verify connection is secure. **B.** Turn down the intensity. Rotate the Lead Wires 90 deg. If still intermittent, replace lead wire. **C.** If still intermittent after replacing lead wire, a component may have failed. Call the repair department.
	Preprogrammed Regimen in use.	Some programs will seem intermittent. This is expected. Refer to "Preprogrammed & Custom Regimens" on page 22 for descriptions.

Troubleshooting

Intensity Auto-Lock:

Once you have started therapy and left the intensity level constant for 20 seconds, the device will lock to prevent accidental increases to intensity. You will see a lock symbol appear in the middle of the screen to indicate that this safety feature is in effect.

To unlock and increase intensity, press the button to decrease the intensity first, at which point the device will unlock and allow you to turn the intensity up.

Open Load Detection:

If the intensity of either channel is above 4.5, the Continuum checks to make sure that there is good contact between the device and the patient. If bad contact is detected, the text "OPEN" will be displayed instead of the intensity, and the intensity on both channels will go to zero. The treatment timer will stop.

To resume treatment, assure that the leadwire is fully connected to the device and to the electrodes, and that there is good contact between the electrodes and the skin. Then increase the intensity to the desired level. If the problem persists, replace the leadwires and electrodes, or contact the Empi Repair Department for assistance (800.862.2343).

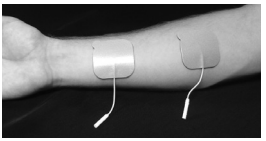
Battery Display:

The battery icon on the top left corner of the display shows the charged state of the battery. This icon will show full for new alkaline batteries, but less than full for fully charged rechargeable batteries.

Low battery voltage is indicated by a flashing battery indicator. The device will display a low voltage message and power down if the battery voltage is too low. For more information, see "Changing the Batteries" on page 17.

To self-test for any of the above, perform the following steps:

1. Place new batteries in the device.
2. Verify the device is off.
3. Insert one new lead wire into two new electrodes.
4. Place the new electrodes on your forearm as shown in the figure below.



5. Insert the lead wire in Channel 1.
6. Turn your device on.
7. Select a TENS knee program. This is a continuous treatment program.
8. Slowly increase the amplitude (intensity) until you can feel it. If you do not get any sensation, lower the amplitude (intensity) to zero and rotate the lead wire 90 degrees. Slowly increase the amplitude (intensity).
9. If there is no sensation, call the repair department.
10. If sensation is felt - even if weak, = device is working properly. You may need to reposition the electrodes or contact your clinician.
11. Repeat Steps 1 through 10 for Channel 2.

Limited Warranty

Warning

While, in the opinion of Empi ("Empi"), the use of the Empi Continuum ("the Product") has met with some success, Empi makes no warranties to the purchaser as to the effectiveness of the product.

Warranty

A. Empi warrants to the initial Purchaser ("Purchaser") (and to no other person) that the Product (with the exclusion of accessories such as chargers, rechargeable batteries, electrodes, lead wires, tape adhesive patches and electrode cream) and the component parts thereof, distributed or manufactured by Empi, shall be free from defects in the workmanship and materials for three years from the initial date of purchase from Empi (the "Warranty Period").

B. Accessories including, but not limited to, chargers, rechargeable batteries, electrodes, lead wires, tape adhesive patches and electrode cream are excluded from the Warranty and sold "AS IS" because their structure is such that they may be easily damaged before or during use.

Limitation of Liabilities and Disclaimer of Warranties

A. Empi's sole obligation in the case of any breach of its warranties set forth in Paragraph A above, shall be, at Empi's option, to repair or replace the Product without charge to Purchaser or to refund the purchase price of the Product. In order to recover under this Warranty, Purchaser must send Empi written notice of the defect (setting forth the problem in reasonable detail) prior to expiration of the Warranty Period, and within 30 days of discovery of the defect. Upon Empi's written request and authorization, Purchaser shall return the Product to Empi, freight and insurance prepaid, for inspection. Notice and return shipment shall be sent to Empi at 47492 Hwy. 22, Clear Lake, South Dakota 57226, USA, or to an Empi Authorized Service Center. To locate the appropriate Service Center outside of North America, or to request shipment approval, contact Empi directly. Empi will not be responsible for damage due to improper packaging or shipment. If Empi determines in its sole reasonable discretion that the Product contains defective workmanship or materials, Empi will refund to the Purchaser, the purchase price for the defective product, or return the repaired Product or a replacement thereof to Purchaser, the purchase price for the defective product, or return the repaired Product or a replacement

Limitation of Liabilities and Disclaimer of Warranties

thereof to Purchaser, freight and insurance prepaid, as soon as reasonably possible following receipt of the Product by Empi. Empi determines in its sole reasonable discretion that the Product does not contain defective workmanship or materials, Empi will return the Product to the Purchaser, freight and insurance billed to the Purchaser.

B. This Warranty is voided immediately as to any Product which has been repaired or modified by any person other than authorized employees or agents of Empi or which has been subjected to misuse, abuse, neglect, damage in transit, accident or negligence.

C. Except as provided in paragraph A, the product is being sold on an as is basis, all accessories are sold as is, and the entire risk as to the quality and performance of the product is with purchaser. The warranty provided in paragraph A is intended solely for the benefit of the initial purchaser and Empi disclaims all other warranties, express or implied including, but not limited to, any implied warranties of merchantability and fitness for a particular purpose; provided, however, that notwithstanding the foregoing sentence, in the event an implied warranty is determined to exist, the period for performance by empi thereunder shall be limited to the lifetime of the initial purchaser. No employee, representative or agent of Empi has any authority to bind empi to any affirmation, representation or warranty except as stated in this written warranty policy.

D. Empi shall not be liable to any person for any direct, indirect, special, incidental or consequential damages, lost profits or medical expenses caused by any defect, failure, malfunction or otherwise of the product, regardless of the form in which any legal or equitable action may be brought against Empi (e.g. contract, negligence or otherwise) the remedy provided in paragraph A above shall constitute purchaser's sole remedy. In no event shall Empi's liability under any cause of action relating to the product exceed the purchase price of the product.

This Warranty gives the Purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow limitations of how long an implied warranty lasts, so the above limitation may not apply to the Purchaser.

REF 199610-001 Continuum Kit

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